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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,083	08/30/2000	Gerald Wynn Hallworth	REF/Hallworth/Div	2803

7590 08/23/2002

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/651,083	HALLWORTH, GERALD WYNN	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19,21-33 and 36-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19,21-33 and 36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/702,700* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the Amendment D, and the Request for Refund, received by the Office on May 30, 2002 and June 20, 2002, respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3,860,618 to Hartley *et al.*. Hartley *et al.* teach that according to a specific feature of their invention, sodium cromoglycate, having an effective particle size of from 0.01 to 10 microns, is useful for mixing with lactose of particle size from 30 to 80 microns in order to produce a composition suitable for inhalation (c 3, l 56-65). Hartley *et al.* also teach that there is no distinction between a single particle of a given size and an agglomerate of the same size which is composed of finer individual particles. Therefore, Hartley *et al.* teach that the lactose particle can be an agglomerate of many smaller particles. This disclosure anticipates the limitations of applicant's claim 18.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that the examples in the reference teach ground crystalline lactose. Additionally, applicant argues that example 1 further teaches that the coarse and fine materials

were mixed together in a mixture in order to break up the agglomerate. The examiner still relies upon the teaching at column 1, lines 52-60, where it states that there is not distinction between a single particle of a given size and an agglomerate of the same size composed of finer individual particles. In addition, the examiner points to column 4, lines 46-55, where Hartley *et al.* state, "by way of comparison composition containing no coarse diluent was prepared and tested in each case. Those compositions containing the coarse carrier were all found to empty from the capsule at a satisfactory rate, in general from 85 to 90 percent of the composition, whereas in the absence of the coarse diluent the emptying rates were much lower, about 15 percent or less, and were unpredictable." Additionally, Hartley *et al.* discuss that the particular compositions which were compared are discussed in table 1. Hartley *et al.* would not have provided information comparing compositions with and without coarse diluent, if all of their compositions ground the lactose to fine particles. Therefore, the examiner relies on her position that Hartley *et al.* teach larger lactose particles made of agglomerated smaller, finer particles. For the above reasons, this rejection is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18, 19, 21-33, 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley *et al.*, as discussed above, and in view of the following comments. Hartley *et al.*

are discussed above as teachings a composition suitable for inhalation comprising sodium cromoglycate and lactose particles. Hartley *et al.* do not teach that the lactose particles are between 150 and 1500 microns. However, it is the position of the examiner that the specific size of the lactose particles is a limitation which would be routinely determined by one of ordinary skill in the art. Furthermore, the determination of a particular size of a lactose pellet, is within the skill of the ordinary worker as part of normal optimization. Additionally, the burden is shifted to applicant to show a finding of unexpected results using specific sizes of lactose particles. Currently, it appears that the teachings of Hartley *et al.* fulfill the same purpose as applicant's claimed invention. Therefore, there appears to be no unexpected result based on the particular size of the lactose particles.

Hartley *et al.* also do not teach each of the specific drugs claimed by applicant. However, Hartley *et al.* do teach that their compositions may contain any of a wide variety of medicaments suitable for administration of inhalation (c 2, l 13-15). Tt is the position of the examiner that one of ordinary skill in the art would have been motivated to use any drug, which is known for use in inhalation therapy, in the composition disclosed by Hartley *et al.*, which is taught to be successful for inhalation use. The expected result would be a successful composition for inhalation therapy.

In conclusion, Hartley *et al.* teach the generic concept that larger lactose particles are successful as carriers for particles of medicaments in order to create inhalation compositions. One of ordinary skill in the art would have been motivated to use any well known inhalation medicament in the teachings of Hartley *et al.*, to create a successful inhalation composition.

Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's argument have been fully considered but are not found to be persuasive. Applicant argues that the limitations of claim 19, that the lactose pellet have a diameter of from 150-1000 microns, is not rendered obvious by the cited reference. The examiner respectfully disagrees. The reference teaches at column 1, that medicaments for administration by inhalation should be able to achieve maximum administration to the lung, and further teaches that the carrier has an effective particle size of from 30 to 80 microns. Hartley *et al.* teach a successful inhalation composition comprising lactose pellets. Therefore, the burden is shifted to applicant to show that by using the claimed particle sizes, applicants achieved surprising, unexpected, and unobvious results. This burden is particularly important, as the reference teaches a composition, with the same components, successful for the same intended purpose. In absence of a showing of unexpected results by applicant, it is deemed obvious to manipulate particle sizes depending on external factors, such as mode of administration and amount of medicament to be delivered.

Additionally, applicant argues that Hartley *et al.*' s teachings that the composition is substantially free of particles in the effective size rage of 11 to 29 microns teaches away from applicant's claim to at least 90% of the particles having less than 15 microns particle size. The examiner respectfully disagrees. The teaching referred to in the reference does not prohibit particles from being less than 15 microns. It simply prefers that they are not between 11 and 29 microns.

Lastly, applicant argues that claims 22 and 23 are not suggested by the reference, because the reference does not refer to the crushing weight at all. However, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

For the above reasons, the rejection is **maintained.**

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep
August 21, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600